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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/083,307	05/22/98	LENTZ M	LEN101

EXAMINER	
NOGGLE, W	
ART UNIT	**PAPER NUMBER**
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PATREA L PABST
ARNALL GOLDEN & GREGORY
2800 ONE ATLANTIC CENTER
1201 W PEACHTREE STREET
ATLANTA GA 30309-3450

DATE MAILED: 05/18/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/083,307	Lentz
Examiner	**Group Art Unit**
William Noggle	3762

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Response

A SHORTENED STATUTORY PERIOD FOR RESPONSE IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a response be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for response specified above is less than thirty (30) days, a response within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for response is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to respond within the set or extended period for response will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

☑ Responsive to communication(s) filed on 4/99.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle,* 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

☑ Claim(s) 1-23 is/are pending in the application.

Of the above claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☑ Claim(s) 1-23 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☑ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 11 9(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received: _____.

Attachment(s)

☑ Information Disclosure Statement(s), PTO-1449, Paper No(s). 4

☐ Interview Summary, PTO-413

☑ Notice of References Cited, PTO-892

☐ Notice of Informal Patent Application, PTO-152

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Other _____

Office Action Summary

*U.S. Government Printing Office: 1997 — 417-376/50309

DETAILED ACTION

Specification

The disclosure is objected to because of the following informalities:

on page 6, line 1, "than" should be changed to --that--,

on page 11, line 4, a period should be added,

and on page 13, line 21, "wityh" should be changed to --with--.

Appropriate correction is required.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of 37 CFR 1.71(a)-(c):

> (a) The specification must include a written description of the invention or discovery and of the manner and process of making and using the same, and is required to be in such full, clear, concise, and exact terms as to enable any person skilled in the art or science to which the invention or discovery appertains, or with which it is most nearly connected, to make and use the same.
>
> (b) The specification must set forth the precise invention for which a patent is solicited, in such manner as to distinguish it from other inventions and from what is old. It must describe completely a specific embodiment of the process, machine, manufacture, composition of matter or improvement invented, and must explain the mode of operation or principle whenever applicable. The best mode contemplated by the inventor of carrying out his invention must be set forth.
>
> (c) In the case of an improvement, the specification must particularly point out the part or parts of the process, machine, manufacture, or composition of matter to which the improvement relates, and the description should be confined to the specific improvement and to such parts as necessarily cooperate with it or as may be necessary to a complete understanding or description of it.

The specification is objected to under 37 CFR 1.71 because failing to provide an adequate written description of the invention and failing to adequately teach how to make and/or use the invention, i.e., failing to provide an enabling disclosure. The specification did not contain the mechanism of the which the ultrafiltration treats tumors. On page 9, lines 10-12, the "presumed mechanism" is not described by the applicant, and as a result the criticality of removing particles having a molecular weight of 120,000 Daltons or less from the patient's blood was also not disclosed by the applicant. Also, the type of vaccine is critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). A specific vaccine against transformed, infected, or diseased tissue was not disclosed in the specification.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-23 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification did not contain the mechanism of the which the ultrafiltration treats tumors. On page 9, lines 10-12, the "presumed mechanism" is not described by the applicant, and

as a result the criticality of removing particles having a molecular weight of 120,000 Daltons or less from the patient's blood was also not disclosed by the applicant.

Claim 8 is rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. The type of vaccine is critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). A specific vaccine against transformed, infected, or diseased tissue was not disclosed in the specification.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 10-14,17, and 23 are rejected under 35 U.S.C. 112, second paragraph, as being vague. In claim 17, the device is described as "removing components in the blood.... and an agent selected from the group...., in a dosage formulation for treatment of the patient." . The applicant needs to make clear that the agent from the selected group is not being removed from the blood, but being added to the kit in a dosage formulation for treatment of the patient.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are

such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-4,8,9,16,18-20, and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lentz (4,708,713).

As to claims 1,2, and 9, Lentz (4,708,713) had disclosed a method and system for inducing an immune response against tumors comprising removing components in the blood having a molecular weight of 200,000 Daltons or less (page 2, lines 8-33). Lentz had also disclosed the system having inlet and outlet means for connection to a pump and tubing to recirculate the blood of a patient through the device (see figure 1). Lentz had not disclosed removing only components present in the blood having a molecular weight of 120,000 Daltons or less. However, Lentz (4,708,713), discloses the claimed invention except for the 120,000 versus the 200,000 Dalton cut off. It would have been obvious to one having ordinary skill in the art at the time the invention was made to change the upper range value from 200,000 to 120,000 Daltons, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

As to claims 3 and 4, the method of claim 1 is obvious in light of Lentz. Lentz had also disclosed the components being removed from one blood volume or in multiple treatments (page 7, lines 50-60).

As to claim 8, the method of claim 1 is obvious in light of Lentz. The use of vaccine against a transformed, infected, or diseased tissue was well known in the art at the time the invention was

made, and the use of a vaccine would have been an obvious choice to a person skilled in the art, for example a medical doctor, at the time the invention was made.

As to claim 16, the system of claim 9 is obvious in light of Lentz. Radiation treatment was well known in the art at the time the invention was made. It was well known in the art at the time the invention was made to combine radiation treatment with another form of cancer treatment.

As to claims 18-20, the system of claim 9 is obvious in light of Lentz. The criticality of the type of filter used in the system was not specified by the applicant, therefore the filter type would be an obvious design choice to a person skilled in the art at the time the invention was made. Obvious design choices do not hold any patentable weight. Lentz had also disclosed the pore size of the filter medium as being between .02 and .05 microns and between .04 and .08 microns (page 10, claims 4 and 5).

As to claim 22, the system of claim 9 is obvious in light of Lentz. Lentz had also disclosed removing components from both the blood and plasma fractions (page 10, claims 4 and 5).

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lentz (4,708,713) in view of Chen et al. (Journal of Neuropathology and Experimental Neurology). The method of claim 1 is obvious in light of Lentz. Lentz had not disclosed the method as removing soluble TNF 1 and 2 receptors from the blood. However, Chen et al. had disclosed the conclusion that TNF receptors help to evade the immune response against a tumor, page 549. Therefore, it would have been obvious to a person skilled in the art at the time the invention was made to

remove TNF 1 and 2 by means of ultrafiltration, because these elements help to evade the immune response against tumors.

Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lentz (4,708,713) in view of Okarma et al. (5,523,096). The system of claim 9 is obvious in light of Lentz. Lentz had not disclosed the device as having an absorption column for removing cytokines. However, Okarma et al. had disclosed an extracorporeal system for removing cytokines from the blood with an absorption matrix, see page 3, line 58 to page 4, line 14. Therefore, it would have been obvious to a person skilled in the art at the time the invention was made to combine Lentz's device with an absorption matrix to remove cytokines from the blood, because removal of cytokines can be used to control the immune system's response to septic shock or other diseases, see page 4, lines 3-5.

Claims 5,6,10-15,17, and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lentz (4,708,713) in view of Wolpe (5,861,483).

As to claims 5,6,12,13,17, and 23, Lentz had disclosed a device for removing ~~only~~ components present in the blood having a molecular weight of 120,000 Daltons or less, see argument for claim 1. Lentz had also disclosed the use of an anticoagulant through the device, page 3, lines 66-68. Lentz had not disclosed the device being in a kit and including an agent selected from the group consisting of anti-angiogenic compounds, procoagulant compounds, cytokines, chemotherapeutic agents, and radiation, in a dosage formulation. However, Wolpe had disclosed the need for stimulatory cytokines, specifically erythropoietin, to maintain a fully functional

immune system, page 1, lines 25-45. The presumed mechanism which Lentz's invention is based on is removing immune inhibitors and letting the body's immune system combat the tumor. Therefore, it would have been obvious to a person skilled in the art at the time the invention was made to add a dose of erythropoietin to a kit including Lentz's device, because erythropoietin works to maintain a fully functional immune system, page 1, lines 25-45.

As to claims 10,11,14, and 15, Lentz and Wolpe had disclosed the claimed invention except for the use of chemotherapeutic agents, specifically alkylating agents, doxyrubicin, cardoplatinum, cisplatinum, and taxol, procoagulant compounds, or anti-angiogenic compounds. It would have been obvious to one having ordinary skill in the art at the time the invention was made to simply replace erythropoietin with one of the above listed compounds or agents, since it has been held to be within the general skill of a worker in the art to select a known compound or agent on the basis of its suitability to the treatment of transformed, infected, or diseased tissue as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William Noggle whose telephone number is (703) 308-4543.

WN

May 13, 1999

RONALD STRIGHT
PRIMARY EXAMINER